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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,320	07/18/2001	Avi Ashkenazi	10466/117	9471

30313 7590 09/27/2002

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary

Application No.	Applicant(s)
09/909,320	Ashkenazi et al
Examiner	**Art Unit**
Fozia Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 26, 2002*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *39-58* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *39-58* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's preliminary amendment canceling claims 1-38 and adding new claims 39-58 filed on 18 July 2001 in Paper No:10 is acknowledged.

Thus claims 39-58 are pending and under consideration

Priority

2. Priority given to some parent cases but not others:

According to the priority statement of 08/26/02, it appears that the claimed subject matter defined in the instant application is disclosed in the parent application serial no. 09/665,350, filed on 09/18/2000, which is a continuation of PCT/US00/0441, which claims priority through a series of CIP applications under 35 U.S.C. to US Provisional Application 60/066772 filed 11/24/1997. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is not supported by the disclosure in application serial no. 60/066772, filed 11/24-1997, because, although the nucleic acid encoding the amino acid sequence of PRO343 is disclosed in figure 28 (SEQ ID NO:15) of 60/066772 are contemplated on pages 29-35 of 60/066772, the parent application does not provide a specific and substantial asserted utility or a well established utility for the claimed invention. Accordingly, the subject matter defined in claims 39-58 has an effective filing date of 07/18/2001 which is the filing date of the current application.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 07/11/2001 which specifically supports the particular claim limitation for

each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 07/18/2001.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 154, line 17. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. Please examine the specification carefully for any other hyperlinks in the text and delete them. See MPEP § 608.01.

Claim Rejections - 35 U.S.C. § 101/112

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4a. Claims 39-58 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 39-58 of the instant invention are directed to an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:262, which encodes the polypeptide of SEQ ID NO:263. The specification describes the polypeptide of SEQ ID NO:263 as comprising 317 amino acid residues and refers it to PRO343, (page 50, line 19-21). The PRO343 is described as having a signal sequence, N-glycosylation site, glycoaminoglycan attachment site, casein kinase II phosphorylation site, Tyrosine kinase phosphorylation site and N-myristoylation site, (see figure 98). However, besides these structural characterizations, the specification does not disclose any information regarding physiologic activity or functional characteristics of the PRO343 polypeptide.

Instant specification demonstrates that PRO343 along with many of the other proteins disclosed in the instant specification, are expressed in lung and colon primary tumors and cell line models, (see table 9 on pages 230-234). However, it does not describe the significance of this expression, nor does it compare the expression of PRO343 in normal lung and colon tissues to the expression of said protein in the lung and colon tumors or tumor cell lines. The specification establishes no connection between the expression of said polypeptide and developing lung or colon tumors. The specification provides no working examples as to the activity of the PRO343 polypeptide, and one of ordinary skill in the art would not be able to predict what activity would be possessed by the protein of the instant application, based solely it might be expressed in some primary lung or colon tumors or cell lines. Thus, since instant specification provides no information regarding the physiological significance or functional characteristics of the polypeptide of SEQ ID NO:263 (PRO343 polypeptide), both PRO343 polypeptide and the nucleic acid encoding it, lack specific asserted utility or a well established utility.

4b. Claims 39-58 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. No biological activity was assayed or determined for the PRO343 polypeptide. Therefore, there is no specific and substantial asserted utility or well established the PRO343 polypeptide or the nucleic acid encoding it . Although the specification describes the structure of PRO343 polypeptide, and discloses the nucleotide sequence of the nucleic acid encoding it, the skilled artisan would not know how to use said PRO343 polypeptide or the nucleic acid encoding

it, because Applicants do not provide any information regarding biological activity or physiological characterization of said polypeptide.

4c. Claims 39-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Should Applicants establish an activity for the polypeptide of SEQ ID NO: 263 encoded by the polynucleotide of SEQ ID NO: 262, instant specification would still fail to adequately describe and enable an isolated polynucleotide comprising a nucleic acid that is at least 80%, 85%, 90%, 95% or 99% to the polynucleotide of SEQ ID NO:262 that encodes the polypeptide of SEQ ID NO: 263. The claims are drawn to polynucleotides having at least 80%, 85%, 90%, 95% or 99% sequence identity with a particular disclosed sequence. Although the claims require that the claimed nucleic acid should encode the polypeptide of SEQ ID NO:263, it does not provide any particular conserved structure, or other distinguishing features which would enable a polynucleotide having at least 80%, 85%, 90%, 95% or 99% to the polynucleotide of SEQ ID NO:262 to encode the polypeptide of SEQ ID NO:263. Thus, the claims are drawn to a genus of polynucleotides that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed

product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

Therefore, only isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO: 262, encoding the polypeptide of SEQ ID NO:263, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that

Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

4d. Claims 39-44, 51, 52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 39-44, 51, 52 are rejected, because the claims are drawn to a "cDNA deposited under ATCC accession number 209481". It is apparent that the cDNA is required to practice the claimed invention. As such said cDNA must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If the cDNA is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of this cDNA.

The specification, provides an ATCC accession number for the claimed cDNA, however, the specification lacks complete deposit information for the deposit of the cDNA. If a deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration

number showing that (a) during pendency of the application, access to the invention will be afforded to the Commissioner upon request, (b) all restrictions upon availability to the public will be irrevocable removed upon granting of the patent, © the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer, (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807) and (e) the deposit will be replaced if it should ever become inviable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 52-54 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claims 52-53 are rejected as vague and indefinite because the claims recite "An isolated nucleic acid that hybridizes under stringent hybridization conditions....", which is a conditional term and renders the claims indefinite. Furthermore, some nucleic acids which might hybridize under conditions of moderate stringency, for example, would fail to hybridize at all under conditions of high stringency. This rejection could be obviated by supplying specific conditions supported by the specification which Applicants consider to be "stringent."

Claim Rejections - 35 U.S.C. § 102 (b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6a. Claims 39, 52-58 are rejected under 35 U.S.C *§ 102*(b) as being anticipated by Fuso Pharmaceuticals Ind. Ltd (WO 200031277; published 02 June 2000).

Fuso Pharmaceuticals Ind. Ltd discloses an isolated nucleic acid which encodes a novel serine protease, designated as BSSP4, a vector and transformants comprising said nucleic acid. The nucleic acid discloses in the WO 200031277 reference shares 84% homology to the nucleic acid of SEQ ID NO:262 claimed in the instant application. See attached copies of the comparison of SEQ ID NO:262 claimed in the instant invention and the sequences of the references (SEQUENCE COMPARISON 'A'). Therefore, since the WO 200031277 reference discloses a nucleic acid that shares 84% to the nucleic of SEQ ID NO:262, a vector and a host that comprise said nucleic acid, it anticipates the instant claims 39, 55-58 in the absence of any evidence to the contrary.

With respect to the "stringent hybridization...." limitation recited in claims 52- 54 the nucleic acid disclosed in WO 200031277 would be expected to hybridize to the nucleic acid of SEQ ID NO:262..

Claim Rejections - 35 U.S.C. § 102 (a)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6b. Claims 39-41, 52-54 are rejected under 35 U.S.C *§ 102*(a) as being anticipated by Yamaguchi et al (May 2001).

Yamaguchi et al disclose the cloning and characterization of a human brain-specific serine protease, (hBSSP-4). The nucleic acid disclosed by Yamaguchi et al shares 93.1% homology to the nucleic acid of SEQ ID NO:262 claimed in the instant application. See attached copies of the comparison of SEQ ID NO:262 claimed in the instant invention and the sequences of the references (SEQUENCE COMPARISON 'B'). Therefore, since the Yamaguchi et al reference discloses a nucleic acid that shares 93.1% to the nucleic of SEQ ID NO:262 , it anticipates the instant claims 39-41, in the absence of any evidence to the contrary.

With respect to the "stringent hybridization...." limitation recited in claims 52- 54 the nucleic acid disclosed by Yamaguchi et al would be expected to hybridize to the nucleic acid of SEQ ID NO:262, thus anticipating claims 52-54.

Conclusion

7. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursdays from 7:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Art Unit: 1647

Fozia Hamud
Patent Examiner
Art Unit 1647
26 September 2002

YVONNE EYLER, PH.D
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